

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER 11 OF THE NAFTA**  
**AND THE UNCITRAL ARBITRATION RULES (1976)**

**BETWEEN:**

**APOTEX INC.**

**CLAIMANT**

**– AND –**

**THE GOVERNMENT OF THE UNITED STATES OF AMERICA**

**RESPONDENT**

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**PROCEDURAL ORDER NO.1**

16 December 2010

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**THE ARBITRAL TRIBUNAL:**

Hon. Fern M. Smith  
Mr Clifford M. Davidson  
Mr Toby T. Landau QC (*Presiding Arbitrator*)

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This **Procedural Order No.1** sets out agreed terms of appointment of the Arbitral Tribunal, and procedural rules that shall govern this arbitration.

## **I. SUBMISSION OF CLAIMS**

1. This arbitration comprises two separate claims, commenced by two separate Notices of Arbitration. The parties have agreed that, for the time being, until resolution of jurisdictional issues, and without prejudice to any future application, the two claims shall be heard concurrently, but not consolidated.
2. The Respondent received Claimant's Notice of Arbitration dated 10 December 2008, on 11 December 2008. The Respondent received Claimant's Notice of Arbitration dated 4 June 2009, on 5 June 2009.
3. By agreement of the parties, the Claimant's application to stay its Notice of Arbitration dated 4 June 2009 has been withdrawn, without waiving its right to reintroduce the same after resolution of the jurisdiction issues.

## **II. THE PARTIES**

4. *The Claimant:*                      The Claimant in this arbitration is:

Apotex Inc.  
150 Signet Drive  
Weston, Ontario  
Canada  
M91 1T9

Tel: +1 416 401 7701

Fax: +1 416 268 1662

Attention:

Shashank Upadhye, Esq., Vice President – Global Head of Intellectual Property

5. *The Claimant's Representation (Art 4 of the UNCITRAL Rules):* The Claimant is represented in this arbitration by:

Rakoczy Molino Mazzochi Siwik LLP  
6 West Hubbard Street, Suite 500  
Chicago, Illinois 60654  
USA

Tel: + 1 312 222 6301  
Fax: + 1 312 222 6321

Attention:

William A. Rakoczy:	<b>wrakoczy@rmmslegal.com</b>
Lara E. FitzSimmons:	<b>lfitzsimmons@rmmslegal.com</b>
Robert M. Teigen:	<b>bteigen@rmmslegal.com</b>

6. *The Respondent:* The Respondent in this arbitration is:

The Government of the United States of America  
c/o  
Office of the Assistant Legal Adviser  
for International Claims and Investment Disputes (L/CID)  
U.S. Department of State  
2430 E Street, N.W.  
Suite 203, South Building  
Washington, D.C. 20037-2800  
USA

7. *The Respondent's Representation (Art 4 of the UNCITRAL Rules):* The Respondent is represented in this arbitration by:

Office of International Claims and Investment Disputes  
Office of the Legal Adviser  
U.S. Department of State  
2430 E Street, N.W.  
Suite 203, South Building  
Washington, D.C. 20037-2800  
USA

Tel: + 1 202 776 8360  
Fax: + 1 202 776 8389

Attention:

Jeffrey D. Kovar:	<b>kovarjd@state.gov</b>
Lisa J. Grosh:	<b>groshlj@state.gov</b>
Mark E. Feldman:	<b>feldmanme@state.gov</b>

### **III. THE ARBITRAL TRIBUNAL**

8. *Constitution of the Arbitral Tribunal (Art 1123 of the NAFTA):* The parties agree and confirm that the Arbitral Tribunal has been duly constituted in accordance with Article 1123 of the NAFTA.
9. The parties confirm that they waive any objection to the appointment of the Arbitral Tribunal on the grounds of conflicts of interest and/or lack of independence or impartiality in respect of all matters known to them at the date of this **Procedural Order No 1**.
10. *Contact Details:* The contact details for each member of the Arbitral Tribunal for the purposes of this arbitration are as follows:

**Mr Toby T. Landau QC** (*Presiding Arbitrator*)

Essex Court Chambers  
24 Lincoln's Inn Fields  
London, WC2A 3EG  
UK

Tel: + 44 207 813 8000  
Fax: + 44 207 813 8080  
Email: **tlandau@essexcourt.net / ttlandau@aol.com**

**Mr Clifford M. Davidson**

Davidson, Davidson & Kappel, LLC

485 Seventh Avenue  
New York, NY 10018  
USA

Tel: + 1 212 736 1940  
Fax: + 1 212 736 2427  
Email: [cdavidson@ddkpatent.com](mailto:cdavidson@ddkpatent.com)

**Hon. Fern M. Smith**  
JAMS  
Two Embarcadero Center, Suite 1500  
San Francisco,  
CA 94111  
USA

Tel: + 1 415 982 5267  
Fax: + 1 415 982 5287  
Email: [fsmith@jamsadr.com](mailto:fsmith@jamsadr.com) and [eschuster@jamsadr.com](mailto:eschuster@jamsadr.com)

#### **IV. ADMINISTRATION OF THE ARBITRATION**

11. *Administering Authority:* With the agreement of the parties, the Secretariat of the International Centre for Settlement of Investment Disputes (“ICSID”) shall render full administrative services in relation to this arbitration similar to those rendered in arbitrations under the ICSID Additional Facility Rules. The cost of ICSID’s services shall be included in the costs of the arbitration. The contact details for ICSID for the purposes of this arbitration are as follows:

Aurélia Antonietti  
International Centre for Settlement of Investment Disputes (ICSID)  
The World Bank Group  
1818 H Street, NW  
MSN U3-301  
Washington, DC 20433  
USA

Tel: + 1 202 458 7603  
Fax: +1 202 522 2615/2027  
Email: aantonietti@worldbank.org  
ifernandez1@worldbank.org

12. *Assistant to the Arbitral Tribunal:* The Arbitral Tribunal may hire an Assistant to aid the Tribunal in its work, whose compensation will be agreed upon by the parties.

## **V. FEES AND EXPENSES OF THE ARBITRAL TRIBUNAL**

(Arts 38 and 41 of the UNCITRAL Rules)

13. The arbitrators will be remunerated in accordance with the ICSID Schedule of Fees.
14. The arbitrators' disbursements shall be reimbursed in accordance with ICSID practice.
15. Deposits for the fees and disbursements are to be made for the amounts and in the manner as directed from time to time by the ICSID Secretariat in consultation with the Arbitral Tribunal.

## **VI. IMMUNITY FROM SUIT**

16. The arbitrators shall have immunity from suit consistent with applicable U.S. law, including, without limitation, immunity from any judicial process and liability, subject to any applicable mandatory law.

## **VII. APPLICABLE ARBITRATION RULES**

(Art 1120 of the NAFTA)

17. The arbitration shall be conducted in accordance with the UNCITRAL Arbitration Rules (1976) (the "UNCITRAL Rules"), except as modified by the provisions of Section B of NAFTA Chapter 11 (*per* NAFTA Art 1120(2)).

18. The IBA Rules on the Taking of Evidence in International Commercial Arbitration, as revised in 2010 (the “**IBA Rules**”) shall apply to address evidentiary questions, except as set forth in Section X below on issues related to confidentiality.

## **VIII. PLACE OF ARBITRATION AND LOCATION OF HEARINGS**

(Art 1130 of the NAFTA; Art 16 of the UNCITRAL Rules)

19. The legal place (seat) of this arbitration shall be New York, NY, USA.
20. Without prejudice to Articles 16(2)-(4) of the UNCITRAL Rules, all hearings shall be held in Washington D.C., USA, subject to paragraph 21 below.
21. Meetings and hearings may, however, be held at locations other than Washington, D.C., or by telephone or videoconference, if so ordered by the Arbitral Tribunal, after consultation with the parties.
22. Internal meetings of the members of the Arbitral Tribunal may be held at other locations considered appropriate by the Arbitral Tribunal, including by video or telephone conference.

## **IX. LANGUAGE**

(Arts 17 and 25(3) of the UNCITRAL Rules)

23. The arbitration shall be conducted in the English language.
24. Communications, submissions, witness statements and documentary evidence submitted in any other language shall be accompanied by a certified translation.



## **X. CONFIDENTIALITY**

25. All written submissions, hearing transcripts, orders and awards generated during the course of this arbitration shall be made available to the public, subject to the redaction of confidential or otherwise protected information as provided in the “Access to documents” section of the 31 July 2001 Note of Interpretation of the NAFTA Free Trade Commission (“FTC”).
26. Consistent with this objective, all hearings shall be broadcast to the public, via closed-circuit television broadcast or an alternative form of broadcast to be agreed upon by the parties, subject to arrangements to safeguard confidential or otherwise protected information.

## **XI. COMMUNICATIONS**

27. *Routing of Communications:* All notifications and communications between the parties and the Arbitral Tribunal shall be made through the ICSID Secretariat.
28. All notifications and communications to the parties shall be to their respective legal representatives, at the contact details in paras 5, 7 and 32 of this Order.
29. The parties shall not engage in any oral or written communications with any member of the Arbitral Tribunal *ex parte* in connection with the subject matter of the arbitration.
30. The parties shall send copies of correspondence between them to the Arbitral Tribunal (via the ICSID Secretariat), only if the correspondence pertains to a matter in respect of which the Arbitral Tribunal is required to take some action or to be apprised of some relevant event.

31. *Mode of Communication:* All notifications and communications arising in the course of this arbitration shall be deemed to have been validly made by delivery against receipt, registered mail, courier, facsimile transmission, email or any other means of telecommunication that provides a record of the sending thereof. Transmissions by facsimile, email and other means of telecommunication need not be confirmed by a hard copy.

32. *Email Distribution List:* All communications by email shall be sent to the following addresses:

For the Claimant:                      **wrakoczy@rmmslegal.com**  
   **lfitzsimmons@rmmslegal.com**  
   **bteigen@rmmslegal.com**

For the Respondent:                      **kovarjd@state.gov**  
   **groshlj@state.gov**  
   **feldmanme@state.gov**

For the Arbitral Tribunal:                      **tlandau@essexcourt.net**  
   **ttlandau@aol.com**  
   **cdavidson@ddkpatent.com**  
   **fsmith@jamsadr.com**  
   **eschuster@jamsadr.com**

For ICSID:                                      **aantonietti@worldbank.org**  
   **ifernandez1@worldbank.org**

33. *Operative Addresses:* Each party has the obligation to inform the other party and the Arbitral Tribunal of any change of contact information or legal representation immediately. Failing such notification, communications in accordance with the contact details in this Order shall be valid.

34. *Written Filings:* Any and all written documents, witness statements, expert reports and other annexes that must be communicated to the other party shall be done so using the FTP

system provided by the ICSID Secretariat. Documents shall be uploaded to the FTP system on the date on which, pursuant to the schedule, the relevant documents must be sent in hard and/or electronic copy to the ICSID Secretariat.

35. The uploading of all documents to the FTP system shall be notified forthwith to all other parties, and the ICSID Secretariat. Notification emails will also contain as an attachment the memorial or other substantive written submission (excluding exhibits) that is the subject of the upload.
36. All files on the FTP system must be downloaded within 60 days.
37. In addition, three hard copies of every filing shall also be forwarded to the ICSID Secretariat.
38. *Date of Receipt:* The date of receipt by the ICSID Secretariat shall be deemed the date of receipt by the Tribunal of a submission, notification or communication. When filings are communicated through the FTP portal, the date of the upload to the FTP system shall, for all purposes, be deemed the relevant time. In the event of technical difficulties, the relevant time will be the date of the notification email referred to in paragraph 35 above.

## **XII. FORMAT FOR WRITTEN SUBMISSIONS AND EXHIBITS**

39. *Hard & Soft Copies:* Written pleadings, submissions, evidence, exhibits and other formal documents which are the subject of any Procedural Order, shall normally be served in electronic format (and whenever possible in searchable “pdf” format or Microsoft “Word”) (with three hard copies filed with the ICSID Secretariat).
40. *Written Submissions:* Each written submission shall attach all documents, authorities, witness statements and expert reports relied upon.

41. Each party's Statement of Claim or Defense shall include a brief chronology of key events.
42. All written submissions are to contain numbered paragraphs.
43. *Exhibits:* All references to exhibits shall be specific, identifying those parts of the document that are relied upon.
44. Each written submission shall include an index of all exhibits referred to.
45. Exhibits are to be arranged as follows:
  - (a) The following documents are to be served in separate binders or sections:
    1. Witness Statements;
    2. Expert Reports (including expert and non-contemporaneous materials referred to);
    3. Legal Authorities.
  - (b) All other documents (*i.e.* all contemporaneous documents) are to be numbered consecutively, with the notation "**C1; C2;** etc" for Claimant's exhibits, and "**R1; R2;** etc" for Respondent's exhibits.
  - (c) Tabs are to be used to separate and (by reference to the index referred to in para 44 above) identify each hard copy exhibit.
  - (d) All legal authorities cited shall be exhibited with the particular passages or sections relied upon highlighted as appropriate.

46. Voluminous or technical documentary evidence may be submitted in the form of a summary of documents, containing lists and/or categories of documents, without prejudice to the right of a party or the Arbitral Tribunal to request the production of any document so listed or categorised and to be provided adequate time for review.
47. Voluminous or technical documentary evidence may be analysed in, and be presented in the form of, reports by qualified persons, such as an accountant, without prejudice to the right of a party or the Arbitral Tribunal to request the production of any document on which any such report is based and to be provided adequate time for review.
48. Copies of documentary evidence shall be assumed to be authentic unless specifically objected to by a party.

### **XIII. WITNESS EVIDENCE**

49. All witness testimony shall initially be adduced by way of witness statements. Each witness statement shall stand as direct evidence / evidence-in-chief at the evidentiary hearing. Any further direct examination / examination-in-chief at the evidentiary hearing shall be strictly limited and, unless the Arbitral Tribunal permits otherwise, shall not introduce any new issues.
50. Each witness statement shall contain:
  - (a) the name and address of the witness;
  - (b) a passport-sized photograph of the witness;
  - (c) a description of his or her relationship to any of the parties (past or present);
  - (d) an executive summary;

- (e) an affirmation of the truth of the witness statement; and
- (f) the witness's signature (including date and place of signature).

- 51. Unless the Arbitral Tribunal decides otherwise in the case of exceptional circumstances, no party shall be entitled to rely upon a witness statement unless the witness in question has been made available for cross-examination, and examination by the Arbitral Tribunal, at the evidentiary hearing.
- 52. With regard to paragraphs 49-51 above, no distinction shall be drawn between the factual testimony of third party witnesses and that of the parties to these proceedings (or their representatives or employees).

#### **XIV. EXPERT EVIDENCE**

- 53. Expert evidence is to be adduced by way of party-appointed experts, who shall produce Expert Reports which are to be attached as exhibits to the parties' written submissions.
- 54. Unless the Tribunal decides otherwise in the case of exceptional circumstances, no party shall be entitled to rely upon an expert report unless the expert in question has been made available for cross-examination, and examination by the Arbitral Tribunal, at the evidentiary hearing.

#### **XV. HEARINGS**

- 55. All hearings shall be simultaneously transcribed using a live transcription software system with immediate dissemination to the parties and the Arbitral Tribunal.

56. The Arbitral Tribunal shall establish, as necessary, procedures and schedules for the correction of transcripts. Any disagreements between the parties on corrections to transcripts shall be resolved by the Arbitral Tribunal.
57. All other detailed directions for hearings shall be the subject of subsequent Orders.

#### **XVI. NON-DISPUTING PARTIES / AMICI**

58. Non-disputing Parties shall have the opportunity to make submissions on questions of NAFTA treaty interpretation, on written notice to the disputing parties, as required by NAFTA Article 1128.
59. The Arbitral Tribunal shall consider any application for leave to file a submission in this arbitration by an intending amicus. Any amicus application for leave to file and accompanying submission shall adhere to the requirements set forth in the recommendations of the FTC on amicus participation, issued on 7 October 2003.
60. The parties shall have the opportunity to make submissions on any application for leave to file a submission in this arbitration by an intending amicus.
61. The Arbitral Tribunal shall issue a ruling on any amicus application for leave to file a submission, taking into account the recommendations of the FTC on amicus participation.

#### **XVII. SEQUENCE OF THE PROCEEDINGS / TIMETABLE**

(Arts 18-25 UNCITRAL Rules)

62. The sequence and timing of the proceedings (with respect to both claims) shall be as follows:

<b>EVENT</b>	<b>DATE</b>
Claimant to file a Statement of Claims	<b>17 January 2011</b>
Respondent to file a Statement of Defense	<b>15 March 2011</b>
Respondent to file Memorial on Objections to Jurisdiction with respect to both claims	<b>16 May 2011</b>
Claimant to file Counter-Memorial on Objections to Jurisdiction	<b>1 August 2011</b>
Deadline for Article 1128 Submissions and Amicus Applications for Leave to File	<b>1 September 2011</b>
Deadline for disputing parties to make submissions, if any, on Amicus Applications for Leave to File	<b>8 September 2011</b>
Deadline for Arbitral Tribunal ruling on Amicus Applications for Leave to File	<b>15 September 2011</b>
Respondent to file Reply on Objections to Jurisdiction	<b>17 October 2011</b>
Claimant to file Rejoinder on Objections to Jurisdiction	<b>16 December 2011</b>
Pre-Hearing Conference Call	<b>24 January 2012</b>
Jurisdictional Hearing	<b>15, 16, 17 February 2012</b>
Award on Jurisdiction	<b>[ TBD ]</b>



63. *Extensions of Time:* Upon the application of a party or on its own motion, extensions of time shall be granted by the Arbitral Tribunal in exceptional cases only, as determined in its discretion (unless agreed between the parties).

#### **XVIII. COSTS OF THE ARBITRATION**

64. Evidence and submissions regarding the quantification of the costs of the arbitration shall be submitted by each party in the form and at a time as will be directed by the Arbitral Tribunal.

#### **XIX. AUTHORITY OF PRESIDING ARBITRATOR**

65. As provided in Art 31(2) of the UNCITRAL Rules, the Presiding Arbitrator is authorised to decide questions of procedure alone, upon reasonable consultation with the other members of the Arbitral Tribunal, and subject to revision, if any, by the Arbitral Tribunal.
66. The Presiding Arbitrator is authorised to sign Procedural Orders on behalf of the Arbitral Tribunal.

#### **XX. STATUS OF ORDERS**

67. Any Order of the Arbitral Tribunal may, at the request of a party or at the Arbitral Tribunal's own initiative, be varied if the circumstances so require.



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**Mr Toby T. Landau QC**  
*on behalf of the Arbitral Tribunal*

**Dated:** 16 December 2010